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Comparison of O2Optix versus other 1-2 week disposable soft contact lenses (EV4-04 trial sub 1 (UNIV))

Abstract

PURPOSE: A wave of silicone hydrogel lenses have recently entered the contact lens market, promising better ocular surface health and superior comfort over that of traditional soft lens designs - a result of their ability to reduce corneal edema by allowing more oxygen to reach the eye. The aim of the present study is to evaluate the subjective and objective differences between conventional 1-2 week soft lenses and a new 2-week silicone hydrogel lens, to determine which modality provides better overall comfort and ocular health.

METHODS: Qualified subjects who had previously worn traditional 1-2 week daily disposable soft lenses were fit with the new silicone hydrogel lens design, and instructed to wear this lens daily, in two-week intervals, for a total of one month. At each of three stages of the trial, measurements of visual acuity, refraction, and biomicroscopy were performed, and subjects were asked to complete a questionnaire about their subjective quality of vision, length of wearing time, and overall comfort with the test lenses, compared to that of their habitual lenses.

RESULTS: Of seventeen enrolled subjects, fifteen completed all three stages of the trial; two subjects dropped out during the study. Significant differences favoring the new silicone hydrogel lens modality included less conjunctival redness (subjective, $p < 0.07$) and limbal redness (objective, $p < 0.03$), as well as a reduced amount of noticeable ocular dryness throughout the day and evening (subjective, $p < 0.05$). Of those who completed all three phases of the trial, twelve subjects preferred the silicone hydrogel lenses over their habitual lenses.

CONCLUSION: In subjects with low-to-moderate myopia who typically experienced symptoms of mild ocular discomfort with their habitual 1-2 week disposable soft contact lenses, switching to a new silicone hydrogel lens modality resulted in better overall lens comfort and significant improvement in symptoms, specifically ocular redness and dryness.

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Master of Science in Vision Science

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Keywords

conjunctival redness, corneal edema, lens comfort, myopia, ocular dryness, oxygen permeable

Subject Categories

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Comparison of O₂OptixTM Versus Other 1-2 Week
Disposable Soft Contact Lenses
(EV4-04 Trial Sub 1 (UNIV))

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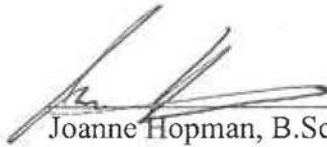
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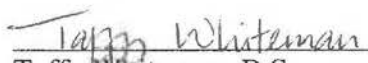
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Comparison of a New Silicone Hydrogel Lens Versus Other 1-2 Week Disposable Soft Contact Lenses

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Neil Montes grew up in San Patricio, New Mexico. He graduated from New Mexico State University in 2001 with a Bachelor of Arts in Biology. He attended Pacific University College of Optometry from 2002-2006 and plans to graduate with a Doctor of Optometry degree in May of 2006. While at Pacific University, he served as Professional Programs Council President of Pacific University, Student Optometric Association Vice President of Pacific University College of Optometry and National Optometric Student Association Vice President of Pacific University College of Optometry. After graduation, Neil plans to return to New Mexico to practice primary care optometry in a private or group practice setting.

Joanne Hopman is an Arizona resident graduating from Northern Arizona State University in 2000 with a Bachelor of Arts in Zoology with a health professional emphasis. In May of 2006 she will graduate with a Doctor of Optometry degree. Once graduation is over she plans to have a private practice in Prescott Arizona.

A native of Colorado, Taffy Whiteman finished her undergraduate training in 1998, receiving a Bachelor of Science degree in Pre-medical Science from Bob Jones University in Greenville, South Carolina. She later attended Pacific University College of Optometry, where she plans to complete her Doctor of Optometry degree in May 2006. Following graduation, Taffy hopes to practice in a disease/co-management setting or a primary care group practice in either Colorado or Oregon.

ABSTRACT

PURPOSE: A wave of silicone hydrogel lenses have recently entered the contact lens market, promising better ocular surface health and superior comfort over that of traditional soft lens designs – a result of their ability to reduce corneal edema by allowing more oxygen to reach the eye. The aim of the present study is to evaluate the subjective and objective differences between conventional 1-2 week soft lenses and a new 2-week silicone hydrogel lens, to determine which modality provides better overall comfort and ocular health. **METHODS:** Qualified subjects who had previously worn traditional 1-2 week daily disposable soft lenses were fit with the new silicone hydrogel lens design, and instructed to wear this lens daily, in two-week intervals, for a total of one month. At each of three stages of the trial, measurements of visual acuity, refraction, and biomicroscopy were performed, and subjects were asked to complete a questionnaire about their subjective quality of vision, length of wearing time, and overall comfort with the test lenses, compared to that of their habitual lenses. **RESULTS:** Of seventeen enrolled subjects, fifteen completed all three stages of the trial; two subjects dropped out during the study. Significant differences favoring the new silicone hydrogel lens modality included less conjunctival redness (subjective, $p<0.07$) and limbal redness (objective, $p<0.03$), as well as a reduced amount of noticeable ocular dryness throughout the day and evening (subjective, $p<0.05$). Of those who completed all three phases of the trial, twelve subjects preferred the silicone hydrogel lenses over their habitual lenses. **CONCLUSION:** In subjects with low-to-moderate myopia who typically experienced symptoms of mild ocular discomfort with their habitual 1-2 week disposable soft contact lenses, switching to a new silicone hydrogel lens modality resulted in better overall lens comfort and significant improvement in symptoms, specifically ocular redness and dryness.

Key words: conjunctival redness, corneal edema, lens comfort, myopia, ocular dryness, oxygen permeable, silicone hydrogel, soft contact lens

INTRODUCTION/ JUSTIFICATION

A number of reports and advertisements have recently been released stating that silicone hydrogel lenses are the most comfortable, healthiest options for contact lens wearers currently on the market. Sweeney et al. states that a superior contact lens will be comfortable and biocompatible to increase safety and efficiency for a unlimited amount of time (3).

When comparing contact lens comfort and health, there are normally two factors considered, the first being a patient's subjective comfort responses to the contact lenses. This is done by tracking a patient's wearing time at the beginning, throughout, and at the end of a normal of day lens wear. Other subjective responses include overall comfort, lens awareness and appearance of the eyes to the patient, i.e. whiteness of the eyes.

The second and more easily measurable factor is the objective appearance of the eyes with lens wear. Researchers commonly use a number of factors to determine comfort and health of the eye. These include but are not limited too, corneal edema, corneal neovascularization, corneal dryness, and limbal and conjunctival redness. These factors are graded in patients with the conventional hydrogel and new silicone hydrogel lenses to determine the differing eye responses (1,3).

Reports suggest that the new wave of silicone hydrogel contact lenses main mode to increase wearing time and improve comfort is by giving higher oxygen transmissibility to the cornea. This oxygen transmissibility has been found to be the most important aspect to reduce corneal swelling, which in turn, increases patient comfort in contact lens wear (2,3).

With these factors in mind, we wished to investigate the subjective and objective differences between a conventional 1-2 week hydrogel lenses versus the new silicone hydrogel lens by Ciba Vision.

METHODS

Investigational Design

This trial was a single-masked, single-group design in which subjects were masked to the brand of contact lenses and to the sponsor of the study. Since the trial included only one test product, the investigators could not be masked.

Fifteen contact lens wearers who were previously adapted to 1-2 week disposable-type spherical soft contact lenses were selected for enrollment in this study. In order to plan for possible withdrawals, two alternate candidates were originally incorporated into the trial, for a total of seventeen participants. All subjects were chosen from a population of Pacific University College of Optometry students who had been wearing soft contact lenses on a regular basis for a minimum of three months prior to the trial. Candidates who wished to be considered for placement in the trial participated in a brief telephone interview where they were asked to respond to a series of questions pertaining to their ocular and systemic health, refractive status, and contact lens-wearing habits. The investigators reviewed each candidate's pertinent ocular and systemic history in order to identify those individuals who satisfactorily met all initial inclusion/exclusion criteria. Subjects were then qualified via telephone and email for their interest and availability for the trial.

Prior to enrollment in the study, all subjects underwent a preliminary vision and ocular health examination, which included measurements of visual acuity with and without habitual contact lenses, a baseline manifest refraction, and biomicroscopy of the anterior segment of both eyes. Subjects were told that they would be trial fitted with a two-week

disposable soft contact lens that is approved for daily wear in the U.S. and Canada, but neither the brand of contact lenses being trialed nor the trial's Sponsor were disclosed. Following this brief description of the study, each participant was required to review and sign the Informed Consent. Subjects were then fit with the new silicone hydrogel lenses in both eyes, and visual acuity and initial subjective comfort with the contacts were recorded. Biomicroscopy was performed to assess each subject's quality of fit with the test lenses, followed by a spherical lens over-refraction in order to verify or refine the prescription.

If subjects met all secondary inclusion/exclusion criteria and were fit with the test lenses successfully at the initial exam, the contacts were dispensed for two weeks of daily wear. A hydrogen peroxide-based lens care system, which was to be utilized throughout the trial for nightly cleansing and lens disinfection, was also provided to each subject, with directions and demonstration for appropriate use. Regular follow-up visits were scheduled during the trial period in order to monitor visual acuity and anterior segment findings with the test lenses. Subjects were instructed to return for a follow-up exam after approximately two weeks and then again at one month following the initial fitting. At the two-week follow-up visit, a second pair of test lenses were dispensed for an additional two weeks of daily wear, altogether totaling one month of wear.

Clinical and subjective data were measured and recorded at the dispensing visit, the two-week follow-up visit, and the one-month follow-up visit. At each of these three stages of the trial, in addition to the clinical examinations described above, subjects were asked to complete a written feedback form containing a series of questions regarding their subjective visual acuity, length of daily wearing time, and overall comfort with the test lenses, compared to that of their habitual soft contact lenses. Each subject's responses to the questionnaire were recorded and reviewed, then combined together with the clinical data, to be evaluated via statistical analysis.

Selection and Enrollment Procedures

In order to qualify for participation in the study, all subjects were required to meet the following criteria:

- Primary Inclusion Criteria
 - o At least 3 months experience wearing 1-2 week disposable-type soft spherical contact lenses
 - o Habitually wears 1-2 week disposable-type soft spherical contact lenses in both eyes at least 5 days per week, at least 8 hours per day, usually for daily wear only
 - o Needs correction for low-to-moderate myopia in both eyes
- Secondary Inclusion Criteria
 - o Correctable to high contrast Snellen VA within 3 letters of the habitual contact lenses at baseline in each eye with the new silicone hydrogel lenses of spherical powers from -1.00 to -6.00 diopters
 - o Refractive astigmatism ≤ 1.00 diopter
 - o On examination, has ocular findings considered to be within normal limits

- Has acceptable or optimal fit with the test lenses and is willing to wear these lenses for the duration of the trial
- Is able to use the hydrogen peroxide-based lens care system for the duration of the trial
- Is willing and able to follow instructions and attend the schedule of follow-up visits

Any of the following conditions excluded a subject from participation in the trial:

- Primary Exclusion Criteria
 - Habitually wears daily disposable-type hydrogel soft contact lenses
 - Habitually wears toric or bifocal lenses
 - Habitually wears monovision correction or a monocular contact lens
 - Requires concurrent ocular medication
 - Eye injury or surgery within twelve weeks immediately prior to enrollment in the study
 - Any systemic disease including insulin-dependent diabetes, autoimmune disease, immunocompromising diseases, connective tissue disease, atopic disease, or use of any medications such as corticosteroids and antimetabolites that may affect the eye or be exaggerated by wearing contact lenses
- Secondary Exclusion Criteria
 - Pre-existing ocular irritation that would preclude contact lens fitting
 - Evidence of systemic or ocular abnormality, infection, or disease likely to affect successful wear of contact lenses or use of the concurrent contact lens care system
 - Allergy or sensitivity to any product used in the study

RESULTS

Seventeen subjects were admitted into the study, and fifteen subjects completed the requirements. The wear time of the lenses ranged from ten hours to eighteen hours a day. When the patients presented to the office in their two-week contact lenses nine out of the fifteen had occasional dryness during the day. At the fourth week visit only two patients had occasional dryness with the silicone hydrogel lenses. Thirteen patients presented with occasional to frequent dryness during the evening. On the fourth week visit only seven patients had dry eyes in the evening during the use of the trial lens. Objectively nine patients originally had mild to moderate red eyes with out silicone hydrogel lenses, and on the fourth week visit three patients had mild red eyes. Limbal redness was noted on eight patients in the first visit and it dropped to three patients after four weeks of silicone hydrogel lens use. See table one.

The p values are shown comparing the trial lenses made of silicone hydrogel material to other two week lenses made of conventional material. Improvements are indicated for the symptoms and signs that have a p value less than 0.5. Table two shows these results.

Two subjects dropped from the study. The first subject was discontinued at the two week follow up due to the need of a higher prescription, which was unavailable through this study. The second subject was then taken out of the study because of product related symptoms and excessive redness in both eyes.

Discussion/ Conclusion

The trial silicone hydrogel contact lenses performed better than the habitual two-week contact lenses. In this study the signs and symptoms showed improvement in most subjects. A healthier lens made from silicone hydrogel is expected to improve the objective and subjective findings (1).

A better lens should give a result of improved health and comfort. The silicone hydrogel lens has both. This modality is great to improve quality of care for contact lens wearing patients because of the improved symptoms and health findings. Overall the silicone hydrogel contact lens was a better two-week lens for most of these subjects (1,2).

The small group, short duration, and type of patients limited the study. Only fifteen patients participated in the trial. A much larger diverse group would be better to analyze the true effects of a silicone hydrogel lens. The study only lasted four weeks, which is an insufficient length of time for a trial. A longer study will allow more time to improve signs and symptoms from wearing silicon hydrogel lenses. One of the biggest drawback of the study is all of the patients are successful two-week contact lens wearers. This does not allow much room for improvement.

Acknowledgements

We would like to thank Ciba Vision for providing O₂Optix™ silicone hydrogel lenses, ClearCare® Contact lens solution, and monetary compensation for the test subjects, Pacific University Family Vision Center for use of the contact lens lab facilities, and the subjects who participated in our study.

References

1. Fonn, Desmond, Sivak, Alisa: Benefits and Challenges of High-Dk/t Materials. Contact Lens Spectrum. February 2005; Vol 20:No. 2
2. Mandell, Robert B.: Contact Lens Practice. Springfield: Charles C. Thomas; 1988. 687-690.
3. Sweeney, D. *Silicone Hyrdrogels: The Rebirth of Continuous Wear Contact Lenses*. Oxford: Butterworth- Heinemann 2000:

Appendix

Table 1		
Symptoms/Signs	Baseline	4 week
Daytime Dryness	9	2
Evening Dryness	13	7
Objective Redness	9	3
Limbal Redness	8	3

Number of subjects with symptom level of occasional or frequent

Table 2		
	Changed?	P Value
Symptoms		
Redness	Improved	.0612
Dryness-Daytime	Improved	.0498
Dryness-Evening	Improved	.0457
Feel Lenses	No Change	n/a
Slit lamp Findings		
Limbal Redness	Improved	.027
Conjunctival Redness	Improved	.1035
All Others	No Change	n/a

Silicone hydrogel two-week contact lenses compared to other two-week contact lenses. Comparison of findings at baseline with those at two weeks was analyzed using Graphpad Instat Version 3.0, Graphpad Software, San Diego, CA. Friedman's test, a non parametric repeated measures analysis of variance, was performed. Directions of change and P value are indicated in the table.